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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Lino Tavares

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/045,607	Applicant(s) TAVARES ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38 and 40-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38, and 40-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In view of the appeal brief filed on November 17, 2010, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Claims 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38, and 40-55 are currently pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 8-11, 13, 14, 16, 20-23, 29, 30, 32, 40-42, 45-49, 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kogan et al. (US 4,910,205, of record) in view of Aslanian et al. (US 6,103,735, IDS filed 06/13/2003).

Applicant Claims

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Applicant's claim 8 is directed to a method of effectively treating seasonal allergic rhinitis, chronic idiopathic urticaria, or both conditions in a human patient, comprising administering loratadine transdermally to the human patient by applying a transdermal delivery system comprising (i) an active agent consisting of loratadine or a pharmaceutically acceptable salt thereof, (ii) a polymer, (iii) a softening agent; and (iv) a solvent, to the skin of a patient, and maintaining said transdermal delivery system in contact with the skin of the patient for at least 5 days, said transdermal delivery system maintaining an effective mean relative release rate to provide a therapeutic blood level of said loratadine within three days from the initiation of the dosing interval, and thereafter maintaining a therapeutic blood level until the end of at least the five-day dosing interval, said transdermal delivery device maintaining a plasma level of loratadine at steady state of about 3 ng/ml;

said transdermal delivery system having a mean relative release rate of from about $2.8 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $16.2 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 24 hours;

from about $2.3 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $13.7 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 48 hours; from about $2.0 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $11.9 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 72 hours;

and a mean relative release rate of from about $1.8 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $9.9 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 96 hours; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human

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cadaver skin, said cell having a receptor chamber containing a 40:60 mixture of ethanol:water.

Applicants' claim 20 is directed to a transdermal delivery system comprising (i) an active agent consisting of loratadine or a pharmaceutically acceptable salt thereof, (ii) a polymer, (iii) a softening agent; and (iv) a solvent,

the transdermal delivery system provides a mean relative release rate of from about $2.8 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $16.2 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 24 hours;

from about $2.3 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $13.7 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 48 hours;

from about $2.0 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $11.9 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 72 hours;

and from about $1.8 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $9.9 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 96 hours; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin and said cell having a receptor chamber containing a 40:60 mixture of ethanol:water; said transdermal delivery system maintaining an effective mean relative release rate to provide a therapeutic blood level of said loratadine within 36 hours from the initiation of the dosing interval, and a plasma level of loratadine of at least about $0.1 \mu\text{g}/\text{ml}$ by about 6 hours after application of said transdermal delivery system onto the skin of a human patient; said transdermal delivery system maintaining a therapeutic blood level until the end of at

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least a five-day dosing interval and a plasma level of loratadine at steady state of about 3 ng/ml.

Applicants' claim 46 is directed to a method of effectively treating seasonal allergic rhinitis, chronic idiopathic urticaria, or both conditions in a human patient, comprising administering loratadine transdermally to the human patient by applying a transdermal delivery system containing loratadine or a pharmaceutically acceptable salt thereof to the skin of a patient, and maintaining said transdermal delivery system in contact with the skin of the patient for at least 5 days, said transdermal delivery system maintaining an effective mean relative release rate to provide a therapeutic blood level of said loratadine within three days from the initiation of the dosing interval, and thereafter maintaining a therapeutic blood level until the end of at least the five-day dosing interval, said transdermal delivery device maintaining a plasma level of loratadine at steady state of about 3 ng/ml;

said transdermal delivery device comprising a backing layer which is substantially impermeable to the loratadine or pharmaceutically acceptable salt thereof', and a reservoir layer consisting essentially of 20 to 90% by weight of a polymeric matrix, 0.1 to 30% by weight of a softening agent; 0.1 to 20% by weight of loratadine base or of a pharmaceutically acceptable salt thereof and 0.1 to 30% by weight of a solvent, for the loratadine or salt thereof;

said transdermal delivery system having a mean relative release rate of from about $2.8 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $16.2 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 24 hours;

from about $2.3 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $13.7 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 48 hours;

from about $2.0 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $11.9 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 72 hours;

and a mean relative release rate of from about $1.8 \mu\text{g}/\text{cm}^2/\text{hr}$ to about $9.9 \mu\text{g}/\text{cm}^2/\text{hr}$ of the transdermal delivery system surface area at 96 hours ; as determined via an in-vitro permeation test utilizing a Valia-Chien cell where the membrane is a human cadaver skin, said cell having a receptor chamber containing a 40:60 mixture of ethanol:water.

The recited plasma levels and release rates are broadened by the term “about”

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Kogan teaches a transdermal delivery system of loratadine for the treatment of allergic conditions (abstract). The system is formed of patch applied to skin for a specific period of time to permit the penetration of a desired amount of loratadine through the skin. The patch comprises a reservoir having 10-20% loratadine; 50-60% solvent; polymer (cellulose polymer), and 20-35% fatty acid esters, i.e. softening agents (col.2, lines 19-29). The patch further comprises a backing layer and a release liner (col.2, line 64; col.3, line 6). The patch will be worn from one to four days and provides a total daily dose of 0.5 to 5 mg (col.2, lines 28-34), which is from $500 \mu\text{g}$ to $5000 \mu\text{g}$ per day for one to four days. The reference disclosed patch size of 15 cm^2 , i.e. average daily released

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dose of $500 \mu\text{g}/15 \text{ cm}^2/\text{day}$ to $5000 \mu\text{g}/15 \text{ cm}^2/\text{day}$. When the dose provided by 15 cm^2 patch is divided by 15 will provide the dose per cm^2 , that is calculated $33.3 \mu\text{g}/\text{cm}^2/\text{day}$ to $333 \mu\text{g}/\text{cm}^2/\text{day}$, which when divided by 24 will provide the hourly dose which is calculated to be $1.4 \mu\text{g}/\text{cm}^2/\text{hr}$ to $14 \mu\text{g}/\text{cm}^2/\text{hr}$. The value from $1.4 \mu\text{g}/\text{cm}^2/\text{hr}$ to $14 \mu\text{g}/\text{cm}^2/\text{hr}$ represents the mean average release rate disclosed by the reference, and applicant claim mean average release rate from $1.8 \mu\text{g}/\text{cm}^2/\text{hr}$ to $9.9 \mu\text{g}/\text{cm}^2/\text{hr}$, which falls within the values disclosed by the reference. The reference disclosed that the dose may be varied depending on the size and age of the patient, and may also depend upon the severity of the condition being treated (col.3, lines 56-60). The frequency of dosage application can be once every 3 days to once every 7 days (col.4, lines 5-10). The claimed delivery rates are met by the reference because the claimed rates are broadened by the term "about" and inclusive of the rates disclosed by the prior art.

With respect to the claimed release rates that are determined by Valia-Chein cell, the prior art is silent regarding the test method and the art does not appear to rely on, or teach the test method. The Patent Office is not equipped with test facilities for result testing. Hence, the instantly claimed release rates are met by the prior art.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Kogan does not explicitly teach the same plasma level of loratadine as instantly claimed. However, Kogan teaches the same daily and hourly delivery rate of loratadine for the same period of time as instantly claimed, as calculated by the examiner, and this

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implies that plasma level of loratadine displayed by Kogan would be the same as claimed. Further, the structure *as claimed* is the same as the prior art and providing 7 days of treatment..

In any event, Aslanian teaches pharmaceutical composition for treating allergic rhinitis comprising therapeutically effective amount of H₁ antagonist (abstract; col.6, lines 8-15). The reference teaches that the pharmaceutical composition is deliverable in transdermal patch (col.7, lines 8-11). A single dosage form of the composition comprises from 1-200 mg of H₁ antagonist and actual dose may be varied depending upon patient's age, sex, weight, and severity of the condition being treated (col.7, lines 23-25; col.2, lines 33-35). Preferred H₁ antagonist is loratadine (col.8, line 66; claims 21 and 32). In present example 8 applicants use 0.12 gm loratadine, i.e. 120 mg. Therefore, in the light of Aslanian teaching, at the time of the invention it was known to load 120 mg of loratadine in a single dosage form as a therapeutically effective dose of loratadine for treating allergic rhinitis.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat allergic rhinitis using transdermal device comprising loratadine, solvent, skin softening agent and polymer as taught by Kogan, and use 1-200 mg of loratadine in the transdermal device as taught by Aslanian. One would have been motivated to do so because Aslanian teaches such an amount in a single dosage

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form, including transdermal patch, is the therapeutically effective dose of loratadine for treating allergic rhinitis. One would reasonably expect effectively treating allergic rhinitis using transdermal device comprising from 1-200 mg loratadine. One would further reasonably expect obtaining plasma levels as instantly claimed because the device taught from the combination of Kogan and Aslanian comprises the same amount of loratadine, solvent, polymer and skin softener and deliver loratadine in the same rate as instantly claimed. Therefore, since the instant specification teaches the same amount of loratidine and as evidenced by Aslanian this is a known and routine amount to be used by the prior art and Kogan teaches the same transdermal structure and treatment days, one would expect that the properties to flow from the combined teaching.

Regarding the claimed release rate of loratadine, Kogan teaches the same mean relative release rate as instantly claim, and combination of Kogan and Aslanian teaches the device comprising the same ingredients and amounts as instantly claimed. Therefore, the amounts and corresponding ratio overlaps with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

The determination of the relative release rate via an in-vitro permeation test utilizing a Valia-Chien cell is not part of the claimed method of treating allergic rhinitis; or

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even a part of the transdermal device that provide particular plasma levels of loratadine. It is only an in-vitro diagnostic test that is expected to provide the same results obtained from two similar delivery devices tested under the same circumstances, and the recitation of this in-vitro test does not impart patentability to claims directed to method of treating allergic rhinitis or claims directed to transdermal device applied to patients to provide specific plasma levels of loratadine, i.e. in vivo use.

5. Claims 35, 36, 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kogan and Aslanian and further in view of Venkateshwaran (US 5,912,009, currently listed on PTO 892).

Applicant Claims

Applicant s' claims 35 and 43 recite specific polymers, and claims 36 and 44 recite specific skin softeners.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combined teachings of Kogan and Aslanian are previously discussed in this office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Kogan teaches polymer and skin softeners in the transdermal composition, however, does not explicitly teach specific polymers and skin softener as instantly claimed by claims 35, 36, 43 and 44.

Venkateshwaran teaches transdermal device to enhance delivery of drugs and not limited to any specific drug (abstract; col.4, lines 3-5). Drugs include antihistaminics (col.5, line 9). The device comprises matrix composition comprising pressure sensitive adhesive polymer including 50-99.75% of acrylate and rubber adhesive and glycols (col.4, lines 52-65; col.8, lines 18-42). The composition further comprises fatty acids esters including those of capric and caprylic acid (col.7, lines 7-9). The composition taught by the reference enhances transdermal delivery of drugs and has good skin tolerability with minimal risks of skin toxicity and irritation (col.3, lines 27-31).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat allergic rhinitis using transdermal device comprising composition comprising loratadine, polymer, skin softening agent and solvent as taught by Kogan combined with Aslanian, and use acrylic or rubber polymers and further use glycol and/or esters of capric or caprylic acid taught by Venkateshwaran in the composition. One would have been motivated to do so because Venkateshwaran teaches that such a composition enhances transdermal delivery of drugs and has good skin tolerability with minimal risks of skin toxicity and irritation. One would reasonably

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expect treating allergic rhinitis using transdermal device comprising composition comprising loratadine, acrylic or rubber adhesive, glycol and esters of capric or caprylic acid wherein the composition is not toxic to the skin nor irritating to the user, therefore improves patient's compliance.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

6. Claims 24, 33-35, 37, 38 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kogan and Aslanian and further in view of Anhauser et al. (US 6,315,854, currently listed on PTO 892).

Applicant Claims

Applicant s' claims 24, 35 and 43 recite specific polymers, claims 37 and 38 recite specific solvent, and claims 33 and 34 recite material of the backing.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The combined teachings of Kogan and Aslanian are previously discussed in this office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims**(MPEP §2141.012)**

Although Kogan teaches polymer and solvents in the transdermal composition, however, does not explicitly teach specific polymers and solvents as instantly claimed by claims 24, 35, 37, 38 and 43, or material of the backing as instantly claimed by claims 33-34.

Anhauser teaches transdermal device for continuous delivery of many active agents with minimal loss of active agent while is looking like a regular band-aid (abstract; col.1, lines 7-22; col.4, lines 1-10). The device comprises reservoir containing the active agent, polymer, and additives. The backing is flexible or non-flexible or containing aluminum foil. Polymers include acrylate, rubber or block copolymers. One of the preferred additives is glutaric acid monomethyl ester. (See col.3, lines 8-34; col.5, lines 15-16).

Finding of Prima Facie Obviousness Rational and Motivation**(MPEP §2142-2143)**

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat allergic rhinitis using transdermal device comprising composition comprising loratadine, polymer, skin softening agent and solvent as taught by Kogan combined with Aslanian, and use acrylic or rubber polymers and add glutaric acid monomethyl ester, as well as use flexible or non-flexible backing as taught by Anhauser. One would have been motivated to do so because Anhauser teaches that a

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transdermal comprising such a composition provides continuous delivery of many active agents with minimal loss of active agent while is looking like a regular band-aid. One would reasonably expect treating allergic rhinitis using transdermal device comprising composition comprising loratadine, acrylic or rubber adhesive, and glutaric acid monomethyl ester, wherein the device provides continuous drug delivery while acceptably appealing to the user.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

7. Claims 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kogan with Aslanian and further in view of Venkateshwaran and Anhauser.

Applicant Claims

Applicant s' claims 50-52 recite specific solvents and skin softeners.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combined teachings of Kogan, Aslanian are previously discussed in this office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Although Kogan teaches skin softeners and solvents in the transdermal composition, however, does not explicitly teach specific skin softener and solvent as instantly claimed by claims 50-52.

Specific skin softeners are taught by Venkateshwaran and specific solvents are taught by Anhauser.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat allergic rhinitis using transdermal device comprising composition comprising loratadine, polymer, skin softening agent and solvent as taught by Kogan combined with Aslanian, and use glycols taught by Venkateshwaran and glutaric acid monomethyl ester taught by Anhauser in the transdermal composition. One would have been motivated to do so because Venkateshwaran teaches that composition comprising glycols enhances transdermal delivery of drugs and has good skin tolerability with minimal risks of skin toxicity and irritation, and because Anhauser teaches that transdermal composition comprising glutaric acid monomethyl ester provides continuous delivery of many active agents with minimal loss of active agent while is looking like a regular band-aid. One would reasonably expect treating allergic

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rhinitis using transdermal device comprising composition comprising loratadine, polymer, glycols, and glutaric acid monomethyl ester, wherein the device is not toxic nor irritating to the skin and provides continuous drug delivery while being acceptably appealing to the user.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made

Response to Arguments

8. Applicant's arguments with respect to claims 8-11,13,14,16, 20, 22-24, 29, 30, 32-38 and 40-55 have been considered but are moot in view of the new ground(s) of rejection over Kogan in view of Aslanian. The new ground of rejection teaches the same amount of loratadine that would display the same claimed plasma release as previously explained in this office action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611

/Isis A Ghali/
Primary Examiner, Art Unit 1611